



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 14, 2014

MEMORANDUM

Subject: Acute Toxicity review for EPA Registration No. 34810-37
Data Package 422396
Product Name: Wexford Disinfectant Wipes

From: Wallace Powell, Biologist *WP*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
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*Chris Jiang
for WPM
11/14/14*

To: Julie Chao, PM 34/ Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Wexford Labs, Inc.

FORMULATION FROM PROPOSED LABEL:

<u>Active Ingredient:</u>	<u>% by weight</u>
Citric acid (EPA PC Code 021801)	0.60
<u>Other Ingredient(s):</u>	<u>99.40</u>
Total:	100.00

BACKGROUND

In support of a registration amendment for the subject product, Wexford Disinfectant Wipes, the applicant has submitted an eye irritation study, MRID 494236-01. For acute oral, acute dermal, and acute inhalation toxicity, eye and skin irritation, and dermal sensitization, the applicant has cited previously cited MRIDs 461138-01 through -06.

WP

RECOMMENDATION

The submitted study and study citations are acceptable. The resulting acute Toxicity Categories are listed in the Summary table below. A review of the submitted study (eye irritation) is appended to this memorandum.

The registrant has confirmed that the test substance in the submitted eye irritation study is the same as their Reg. No. 34810-35 product. This is acceptable.

The cited studies for the other five acute effects were also conducted on the 34810-35 product and were accepted for that product in a 1/5/2005 review, DP 311469 (as a follow-up to a 3/10/2004 review, DP 298432). They were also cited for Wexford Disinfectant Wipes, Reg. No. 34810-37, in support of initial registration.

The 1/5/2005 review also accepted a 2003 eye irritation study, MRID 461138-04. That study and the newly submitted study were both conducted on the Reg. No. 34810-35 product. The Agency does not normally accept repeat studies. However, the formulation does appear to have changed slightly since 2003, enough change to justify a new eye irritation study (even though the formulation still appears similar enough to support the Toxicity Categories for the other acute effects).

The results of the newly submitted eye irritation study place the product in Toxicity Category IV for eye irritation. This replaces the Category III assignment, which was based on the previous eye irritation study.

Summary

The acute toxicity profile of Wexford Disinfectant Wipes is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	461138-01	IV	Cited
Acute Dermal Toxicity	461138-02	IV	Cited
Acute Inhalation Toxicity	461138-03	IV	Cited
Primary Eye Irritation	494236-01	IV	Acceptable
Primary Skin Irritation	461138-05	IV	Cited
Dermal Sensitization	461138-06	Non-sensitizer	Cited

Product Labeling:

The First Aid and human-hazard precautionary statements in the proposed label (EPA Received 7/7/2014) are acceptable. As implied in the proposed label, the signal word CAUTION (following the child hazard warning) and the *Hazard to Humans and Domestic Animals* section and the *First Aid* section, are all optional.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: 34
MRID No.: 494236-01

Reviewer: W. Powell
Study Completion Date: 2/12/2014
Report No.: 37911

Testing Laboratory: Product Safety Labs
Author: Carolyn Lowe

Quality Assurance (40 CFR §160): Included

Test Material: CleanCide READY TO USE
Dosage: 0.1 mL

Species: Rabbit, New Zealand albino
Sex: 3 Females
Age: Young adult
Weight: 2.43 - 2.55 kg
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Deviations from Guideline 870.2400: None noted

Results:

No corneal opacity or iritis was observed in any treated eye. 'Positive' conjunctival irritation was limited to grade 2 on the Draize scale at 1 Hour in 1 of 3 animals, clearing by 24 Hours. The results indicate that the test material was minimally irritating to the eye.

Incidence of Irritation

Time Post-Instillation	No. of Animals Testing "Positive" / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctiva	
			Redness	Chemosis
1 hour	0 / 3	0 / 3	1 / 3	0 / 3
24 hours	0 / 3	0 / 3	0 / 3	0 / 3
48 hours	0 / 3	0 / 3	0 / 3	0 / 3
72 hours	0 / 3	0 / 3	0 / 3	0 / 3